In the United States Court of Federal Claims

No. 15-1048
(Filed Under Seal: March 20, 2023)
Reissued: April 5, 2023[1]

DEIDRE HENKEL *and* ALEX HENKEL, *as parents of* V.H., *a minor*,	)
Petitioners,	)
v.	)
SECRETARY OF HEALTH AND HUMAN SERVICES,	)
Respondent.	)

Edward Kraus, Kraus Law Group, Chicago, IL, for petitioners.

Ryan Daniel Pyles, Vaccine/Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, for respondent.

OPINION

***SMITH*, Senior Judge**

Petitioners, Deidre and Alex Henkel, on behalf of their minor child, V.H., seek review of a decision issued by Special Master Herbrina D. Sanders denying their petition for vaccine injury compensation. Petitioners brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10, *et seq*. (the "Vaccine Act"), alleging that the intranasal seasonal influenza ("flu") vaccine ("FluMist") V.H. received on September 24, 2012, caused V.H. to suffer from narcolepsy with cataplexy. The Special Master denied compensation, finding that petitioners did not establish by preponderant evidence that the flu vaccine caused V.H. to develop narcolepsy with cataplexy. Ruling on Entitlement at 2, ECF No. 107 [hereinafter Entitlement Decision]. Petitioners now move for review of this decision. For the reasons that follow, the Court **DENIES** petitioners' Motion for Review.

I. BACKGROUND AND PROCEDURAL HISTORY

V.H. was born on August 3, 2007. Petitioners' Exhibit 1 at 77 [hereinafter PX]. On September 29, 2010, he received his first FluMist vaccination without any recorded

[1] An unredacted version of this opinion was issued under seal on March 20, 2023. The parties were given an opportunity to propose redactions, but no such proposals were made.

complications. *See* PX1 at 83. On June 29, 2011, V.H. and his mother visited family nurse practitioner ("FNP") Scott Parker at Cedar Valley Medical Clinic reporting that V.H. had symptoms of fatigue and that he "naps frequently and rests a lot during the day." *See* PX4 at 4. FNP Parker diagnosed V.H. with fatigue and Pica.[2] PX4 at 4. V.H.'s bloodwork was normal. PX4 at 18.

On September 24, 2012, V.H. received a second FluMist vaccine intranasally at Color Country Pediatrics. PX1 at 15. On November 20, 2012, V.H. visited FNP Parker at Cedar Valley Medical Clinic for episodic abdominal pain over the previous four days. PX4 at 9. FNP Parker diagnosed V.H. with abdominal pain and his bloodwork was normal. PX4 at 10, 23.

On January 30, 2013, V.H. visited physician's assistant ("PA") Taran Hansen at Color Country Pediatrics. PX1 at 12. V.H.'s mother reported that V.H. had "been sleeping more than normal [and] acting generally more fatigued than normal for the past [eight] weeks." PX1 at 12. V.H.'s physical exam was normal, and PA Hansen assessed him with fatigue. PX1 at 13. PA Hansen ordered bloodwork which was normal. PX1 at 13–14, 79. On February 20, 2013, V.H. returned to PA Hansen for a well-child exam. PX1 at 8. Petitioners reported that "[o]ver the past [one to two] months, [they] have noted [V.H.] being far more sleepy than normal, despite intact, preserved sleep hygiene at nights [and] allowing him at least [ten] hours of sleep per night." PX1 at 8. Petitioners noted that V.H. "has now started falling fast asleep (within minutes) during dinner, sitting upright, etc[.] during the day." PX1 at 8. Petitioners stated that V.H. had a "[history] of sleepwalking and nighttime terrors[,] which have also persisted." PX1 at 8. During this visit, V.H. received DTaP, IPV, and MMR vaccinations. PX1 at 10–11. PA Hansen diagnosed V.H. with transient excessive sleepiness and referred him to Primary Children's Hospital for a sleep study. PX1 at 10–11.

On March 27, 2013, V.H. visited Kathleen Pfeffer, M.D., at Utah Sleep and Pulmonary Specialists for a sleep study. *See* PX3 at 15. Dr. Pfeffer noted that "[V.H.] did receive a flue [sic] vaccine at the end of September 2012 with sleepiness beginning over the last several months." PX3 at 15. On April 13, 2013, V.H. underwent a Multiple Sleep Latency Test following a repeat sleep study. PX3 at 38–39. Dr. Pfeffer stated that V.H.'s "sleep study suggests idiopathic hypersomnia, rather than narcolepsy, although [it] could evolve into narcolepsy." PX3 at 39. Dr. Pfeffer concluded her impressions on the sleep study as follows, "I have to wonder if this is related to the influenza vaccine." PX3 at 39.

On September 18, 2013, V.H. visited Emmanuel Mignot, M.D., and resident physician Nevin Arora, M.D., at Stanford Sleep Medicine Center for Narcolepsy. *See* PX5 at 3, 7–8; PX3 at 74. Blood tests revealed that V.H. had a gene marker associated with narcolepsy, DQB1*0602. PX5 at 4. Dr. Arora observed that V.H. exhibited symptoms of "narcolepsy with cataplexy after Flumyst [sic] vaccine" and diagnosed V.H. with "narcolepsy with cataplexy," with Dr. Mignot concurring. PX5 at 7–8.

[2] Pica refers to "compulsive eating of nonnutritive substances[.]" *PICA*, DORLAND'S, https://www.dorlandsonline.com (last visited February 25, 2023).

On July 21, 2014, V.H. returned to Dr. Pfeffer for a follow-up appointment. PX3 at 75. Dr. Pfeffer stated that V.H. had been diagnosed with narcolepsy and cataplexy, which "may or may not have been related to a flu vaccine." PX3 at 75.

On September 21, 2015, petitioners filed a Petition with the Office of Special Masters, seeking compensation for vaccine-related injuries. *See generally* Petition, ECF No. 1. On September 22, 2015, petitioners filed medical records, Ms. Deidre Henkel's affidavit, and medical literature as exhibits. PX1–10; PX11–13. On December 24, 2015, respondent filed its Vaccine Rule 4(c) report. *See generally* Respondent's Rule 4(c) Report, ECF No. 13.

The case was reassigned to Special Master Sanders on January 11, 2017. *See* Order Reassigning Case, ECF No. 27. On August 31, 2022, Special Master Sanders denied petitioners' claim, finding that petitioners failed to prove by preponderant evidence that V.H.'s narcolepsy was caused by his September 24, 2012 flu vaccination. *See* Entitlement Decision at 56. On September 30, 2022, petitioners filed their Motion for Review of Special Master Sanders's decision with this Court. *See* Motion for Review, ECF No. 108 [hereinafter Pets.' MFR]. On October 31, 2022, respondent filed its Response to petitioners' Motion for Review. *See* Respondent's Response to Petitioners' Motion for Review, ECF No. 113 [hereinafter Resp.'s Resp. to MFR]. Petitioners' Motion is fully briefed and ripe for review.

II. STANDARD OF REVIEW

Under the Vaccine Act, this Court may review a Special Master's decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing such a request, this Court may:

> (A) uphold the findings of fact and conclusions of law . . . ,
>
> (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. § 300aa-12(e)(2)(A)–(C). "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

When reviewing a special master's decision, this Court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009). This Court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)). "[R]eversible error is extremely difficult to

demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotations omitted). "[A]s long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.'" *Porter*, 663 F.3d at 1249 (quoting *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

III. DISCUSSION

The Vaccine Act provides that causation is established through (1) a statutorily prescribed presumption of causation when the injury falls under the Vaccine Injury Table ("Table injury"); or (2) proof of causation-in-fact when the injury is not listed in the Vaccine Injury Table ("off-Table injury"). *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Petitioners do not allege a Table injury in this case; thus, they must prove that V.H.'s injury was caused-in-fact by the vaccine. *See id.* (citing 42 U.S.C. §§ 300aa–13(a)(1), –11(c)(1)(C)(ii)(I)). To prove causation-in-fact, a petitioner must

> show by preponderant evidence that the vaccination brought about [petitioner's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; *(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.*

Id. (emphasis added).

Before addressing petitioners' specific arguments regarding *Althen* Prongs II and III, the Court will address a disagreement between the parties regarding the relationship between the three prongs. Petitioners argue that because the three *Althen* prongs are part of an overlapping and collaborative analysis, the Special Master erred by not considering evidence petitioners put forth to satisfy Prong I in her Prongs II and III analyses. *See* Pets.' MFR at 15 (citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006)), 20. Respondent argues that petitioners' Prong II argument "amounts to no more than a restatement of their general theory of causation [in other words, their successful Prong I argument], without providing any evidence that the vaccine did cause V.H.'s narcolepsy in this particular case." Resp.'s Resp. to MFR at 8. Further, respondent argues that "[i]f petitioners were able to establish case specific causation by the alleged injury merely following vaccination during a certain timeframe, then that would essentially render *Althen* prong two as meaningless." *Id.* at 9. Regarding Prong III, respondent argues that petitioners' expert Dr. Steinman's testimony on temporal proximity was based on ipse dixit, and the Special Master committed no error in finding it insufficient to satisfy Prong III, even though she found it sufficient to satisfy Prong I. *See id.* at 16.

While evidence used to satisfy one prong of the *Althen* test may overlap to satisfy another prong, a petitioner does not necessarily meet its evidentiary burden for one prong by virtue of providing preponderant evidence for another prong. *See Capizzano*, 440 F.3d at 1326–27. The

Althen prongs are independent obligations, all of which a successful claimant must satisfy. In *Capizzano*, the Federal Circuit explained the following:

> The second prong of the *Althen III* test is not without meaning. There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the vaccine was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Id. at 1327 (emphasis in original). Thus, a claimant could satisfy one or even two of the *Althen* prongs but fail on the remaining prong(s) when the evidence presented is insufficient to satisfy the remaining prong(s). *See K.T. v. Sec'y of Health & Hum. Servs.*, 132 Fed. Cl. 175, 187 (2017) (holding that a special master's finding under Prong III—that petitioner proved a temporal association—did not preclude the Court from finding that petitioner failed to meet her burden under Prong II). With this point in mind, the Court will address petitioners' arguments below.

A. Burden of Proof Under *Althen* Prong II

Petitioners argue that their evidence used to successfully satisfy Prong I was deemed insufficient by the Special Master under Prong II. *See* Pets.' MFR at 14–15. Petitioners argue that, by doing so, the Special Master incorrectly raised the burden of proof. *See id.* Respondent argues that petitioners' Prong II argument "amounts to no more than a restatement of their general theory of causation, without providing any evidence that the vaccine caused V.H.'s narcolepsy in this particular case." Resp.'s Resp. to MFR at 8. The Court is inclined to agree with respondent.

To satisfy Prong II, a petitioner must show by preponderant evidence that the vaccination brought about their injury by providing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. However, the Federal Circuit has made clear that "neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010) (quoting *Althen*, 418 F.3d at 1278). A special master may find evidence from treating physicians unpersuasive when they considered, but did not conclude, that a vaccination caused petitioner's condition. *See Cedillo*, 617 F.3d at 1348 (determining that a special master's decision to attribute little weight to the notations of treating physicians was not arbitrary or capricious when they speculated or noted a link between the vaccination and injury but did not conclude that the vaccine caused the petitioner's injury).

The Special Master's finding on Prong II was not arbitrary, capricious, an abuse of discretion, or contrary to law. The Special Master found portions of Dr. Steinman's expert opinion, V.H.'s medical records, and additional evidence insufficient to satisfy Prong II. *See*

Entitlement Decision at 52–56. Under Prong II, the Special Master determined that Dr. Steinman presented a causation theory based on temporal proximity between flu vaccination and development of narcolepsy. *See id.* at 53. The Special Master stated the following:

> Dr. Steinman's assertion that V.H. experienced a recall response that caused his narcolepsy is based on *temporal proximity alone*. This abductive reasoning that the vaccine must be the cause is not sufficient to meet the standard because, to establish causation, more is needed than a chronological relationship. While Petitioners are not required to present direct evidence of recall/rechallenge, Dr. Steinman has identified recall as the type of immune response that triggered V.H.'s autoimmunity. Dr. Steinman cannot simply state V.H.'s injury is presumed evidence of the recall, the recall is presumed evidence of the autoimmunity, and the autoimmunity is presumed evidence of vaccine causation, without some support that these processes actually occurred in V.H.'s case. Dr. Steinman's conclusions are, by his own concession, speculation based solely on chronology.

Id. at 53–54 (emphasis added). Because petitioners must demonstrate more than a "proximate temporal relationship between vaccine and injury," the Special Master reasonably concluded that Dr. Steinman's expert testimony did not preponderantly support causation. *See Moberly*, 592 F.3d at 1323 (noting that a mere showing of a proximate temporal relationship between vaccine and injury is not sufficient to meet the burden of proof under Prong II).

The Special Master also considered V.H.'s physicians' statements and medical records in her Prong II analysis and found that they did not preponderantly support causation. *See* Entitlement Decision at 52–55. The Special Master reasonably attributed little weight to the opinions of V.H.'s treating physicians because they considered the vaccine as a potential cause of V.H.'s narcolepsy but stopped short of concluding the vaccination was the cause, or the likely cause, of the condition. *See id.* at 54–55 (stating that V.H.'s physician Dr. Pfeffer explained that V.H.'s narcolepsy with cataplexy "may or may not have been related to a flu vaccine"). The Special Master also explained that Drs. Arora's and Mignot's assessment of "narcolepsy with cataplexy *after* Flumyst [sic] vaccine[]" referred to "chronology rather than causation." *See id.* at 55 (emphasis added).

Additionally, the Special Master noted that petitioners' own expert acknowledged that there was nothing in V.H.'s medical records indicating that V.H. experienced an autoimmune process. *See id.* at 53 ("Dr. Steinman acknowledged that there is 'nothing in the medical record' indicating that V.H. experienced an autoimmune process."). Therefore, because none of V.H.'s treating physicians concluded that the vaccine was the cause, or likely cause, of the injury, and because Dr. Steinman testified that nothing in the medical records indicates that V.H. experienced an autoimmune process, the Special Master acted reasonably in attributing little weight to their conclusions. *See Cedillo*, 617 F.3d at 1348 (determining that a special master's decision to attribute little weight to the opinions of treating physicians was not arbitrary or capricious when none of the treating physicians concluded that the vaccine caused the petitioner's injury).

Finally, the Special Master did not raise the burden of proof in finding the evidence sufficient to satisfy Prong I—portions of Dr. Steinman's testimony, petitioners' scientific evidence, V.H.'s physicians' statements, and medical records—insufficient to satisfy Prong II. *See Capizzano*, 440 F.3d at 1326–27. The Special Master reviewed the evidence under Prong II and reasonably concluded that petitioners have not met their evidentiary burden. *See id.* While evidence between prongs may overlap, each prong must be individually satisfied. *See id.* This Court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter*, 663 F.3d at 1249 (citing *Broekelschen*, 618 F.3d at 1349). The Court finds that the Special Master considered the evidence in the record, drew plausible inferences, and articulated a rational basis for her decision. *See Lampe*, 219 F.3d at 1360. Accordingly, the Court finds that the Special Master's finding on Prong II was not arbitrary, capricious, an abuse of discretion, or contrary to law.

B. Burden of Proof Under *Althen* Prong III

Petitioners argue that their evidence used to successfully satisfy Prong I was deemed insufficient by the Special Master under Prong III. *See* Pets.' MFR at 20. Petitioners argue that, by doing so, the Special Master incorrectly raised the burden of proof. *See id.* Respondent argues that the Special Master appropriately weighed the evidence when she found that petitioners had not presented preponderant evidence of a proximate temporal relationship. *See* Resp.'s Resp. to MFR at 18. Specifically, respondent argues that petitioners' expert, Dr. Steinman, based his testimony on ipse dixit, and the Special Master committed no error in deciding that Dr. Steinman's testimony failed to preponderantly support causation. *See id.* at 16–17. The Court is inclined to agree with respondent.

To satisfy Prong III, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1278. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citing *Pafford*, 451 F.3d at 1358). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *de Bazan*, 539 F.3d at 1352. However, "cases in which onset is too soon" also fail to satisfy this Prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*

The Special Master's finding on Prong III was not arbitrary, capricious, an abuse of discretion, or contrary to law. In *de Bazan*, the petitioner's expert relied on scientific studies to support her Prong III theory of a medically appropriate time frame between vaccination and injury. 539 F.3d at 1352–53. The special master in that case found that the expert's testimony and scientific studies were insufficient to satisfy Prong III because the testimony and studies did not support the time frame presented in the petitioner's case. *See id.* Similarly, the Special Master in this case did not find Dr. Steinman's expert testimony sufficient to satisfy Prong III. *See* Entitlement Decision at 56 ("Dr. Steinman has not explained how a recall response would

impact the timing of disease onset following either [a live attenuated influenza vaccine] or an infection."). The Special Master also did not find the scientific studies that Dr. Steinman relied on to be sufficient to satisfy Prong III. *See id.* ("[Petitioners' scientific studies] claimed that narcolepsy following infection with H1N1 occurred six months post vaccination, but that is not the timeframe proposed by Petitioners as appropriate in this case.").

Finally, the Special Master did not raise the burden of proof in finding the evidence sufficient to satisfy Prong I—portions of Dr. Steinman's testimony, petitioners' scientific evidence, V.H.'s physicians' statements, and medical records—insufficient to satisfy Prong III. *See Capizzano*, 440 F.3d at 1326–27. The Special Master reviewed the evidence under Prong III and reasonably concluded that petitioners did not meet their evidentiary burden. *See id.* While evidence between prongs may overlap, each prong must be individually satisfied. *See id.* This Court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter*, 663 F.3d at 1249 (citing *Broekelschen*, 618 F.3d at 1349). The Court finds that the Special Master considered the evidence in the record, drew plausible inferences, and articulated a rational basis for her decision. *See Lampe*, 219 F.3d at 1360. Accordingly, the Court finds that the Special Master's finding on Prong III was not arbitrary, capricious, an abuse of discretion, or contrary to law.

IV. CONCLUSION

For the foregoing reasons, the Court finds that the Special Master did not act arbitrarily, capriciously, contrary to law, or abuse her discretion. Accordingly, the Court upholds the Special Master's decision and **DENIES** petitioners' Motion for Review.

IT IS SO ORDERED.

s/ *Loren A. Smith*

Loren A. Smith,
Senior Judge